



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,469	03/21/2006	Atsushi Ogawa	81844.0038	8944
26/021 7590 03/27/2009 HOGAN & HARTSON LLP. 1999 AVENUE OF THE STARS SUITE 1400 LOS ANGELES, CA 90067				
EXAMINER				
OU, JING RUI				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
03/27/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,469

Applicant(s)

OGAWA ET AL.

Examiner

JING OU

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is responsive to the amendment filed along with the RCE on 01/26/2009. Claims 1-5 and 8-11 are pending. Claims 1 and 11 are independent. Claims 6 and 7 have been cancelled. Claims 10 and 11 are newly added

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/26/2009 has been entered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "clearance" and "coil pitches" in Claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 1 is objected to because of the following informalities: On line 3 of paragraph 2 of claim 1, the recitation "inner peripheries" should be corrected to "inner periphery." Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claim 10, support for the amended recitation "wherein the stretch supporting member extends over the entire region of the coil main

body" cannot be found in the original specification. Therefore, the recitation is considered as new matter. Furthermore, Figures 1 and 2 only shows that the stretch supporting member extends over a portion of the coil main body.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1-5 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 recites the limitation "the clearance" and "the coil pitches" in paragraph 2 of Claim 1 and paragraphs 2 and 3 of Claim 11. There is insufficient antecedent basis for this limitation in the claim.

In Claim 11, it is unclear to the Examiner how the stretch suppressing member has the clearance between the outer periphery of the coil main body and the inner periphery of the stretch suppressing member.

Regarding claim 11, the word "means" is preceded by the word(s) "for separating a coil" and "for suppressing stretch" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 4, and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene, JR. et al (US Pub. No.: 2002/0177855).

In regard to Claim 1, 2, 4, and 8-11, Greene, JR. et al discloses an embolus forming in-vivo indwelling device comprising a coil separating member (24) and a coil main body (coils, 414, Fig. 40A) having flexibility and an stretch suppressing member (inner portion of polymer member 404 located inside the coils 414, Fig. 40A) which is provided on the inner periphery of the coil main body and which is made of a polyvinyl alcohol polymer (Para.[0088]), wherein the stretch supporting member extends over the entire region of the coil main body (Figs. 36 and 39 and Paras. [0085] and [0136]); in the case that the dry stretch suppressing member is provided on the inner periphery of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body (Fig. 40A, since the inner portion of polymer member 404 is locating inside the coils 414, the inner portion of polymer member 404 has a smaller diameter than the coil 414); the stretch suppressing member has a rod-like shape and is provided in the coil main body so as to pass through the coil main body and extend in the coil axial direction of the coil main body (Fig. 40A); and another stretch suppressing member (the outer portion of polymer member 404 located outside the coils 414 and

covers the coils, Fig. 40A) has a cylindrical shape and is provided to cover the entire region of the outer periphery of the coil main body in the coil axial direction.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al (US Pat. No.: 5,846,210) in view of Ken et al (US Pat. No.: 5,853,418).

In regard to Claims 1, 2, 4, 5, and 11, Ogawa et al discloses a medical device comprising a coil separating member (18) and a coil main body (implanted device, 16, Fig. 1) having flexibility and an stretch suppressing member (joint member 15, Figs 1 and 2) which is provided on the inner periphery of the coil main body and which is made of a polyvinyl alcohol polymer (Col. 6, lines 45-49); in the case that the dry stretch suppressing member is provided on the inner periphery of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body (Fig. 2); the stretch suppressing member has a rod-like shape (Col. 7, lines 1-3) and is provided in the coil main body so as to pass through the coil main body and extend in the coil axial direction of the coil main body (Figs. 1 and 2); and the diameter of the stretch suppressing member is smaller than the inner diameter of the coil main body by about 1 to 50% in a dry state (Col. 7, lines 9-14 and 22-27 and Fig. 2).

Ogawa et al does not appear to disclose that the stretch supporting member extends continuously over the entire region of the coil main body.

However, Ken et al discloses a vaso-occlusive coil (100, Fig. 1) comprising a stretch supporting member (108, Fig. 1) extending continuously over the entire region of the coil main body (102, Fig. 1).

Ogawa et al and Ken et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Ogawa et al and Ken et al before him or her, to modify the stretch supporting member to extend continuously over the entire region of the coil main body as taught by Ken et al.

The suggestion/motivation for doing so would have been to prevent stretching of the coil during movement of the coil (Ken et al, see Abstract).

Therefore, it would have been obvious to combine Ken et al with Ogawa et al to obtain the invention as specified in the instant claims.

In regard to Claim 3, Ogawa et al in view of Ken et al discloses all the limitations of the claim as taught above and further discloses the wire constituting the coil main body has a diameter of 0.07 mm, and the coil main body has a coil diameter of 0.1 mm. Ogawa et al does not appear to disclose a coil length of 2 to 500 mm and a number of turns of 1 to 100 per unit length (1mm).

However, applicant should be noted that the coil length and the number of turns are only design choices and within of one of ordinary skill in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a coil length of 2 to 500 mm and a number of turns of 1 to 100 per unit length (1mm), since it has been held that that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

15. Applicant's arguments filed 01/26/2009 have been fully considered but they are not persuasive. The allegation on page 7 of the remarks that the applied references do not disclose or suggest, "in case that the dry stretch suppressing member is provided on the inner peripheries of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body or in case that the dry stretch suppressing member is provided on the outer periphery of the coil main body, the stretch suppressing member has the clearance between the outer periphery of the coil main body and the inner periphery of the stretch suppressing member, and the stretch suppressing member enters the coil pitches of the coil main body as a result of swelling" is incorrect. Greene JR et al discloses that in case that the dry stretch suppressing member is provided on the inner peripheries of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body (Fig. 40A, since the inner portion of polymer member 404 is locating inside the coils 414, the inner portion of polymer member 404 has a smaller diameter than the coil 414) and the stretch suppressing member enters the wire space of the coil main body as a result of swelling (Fig. 40B). In addition, Ogawa et al discloses that in the case that the dry stretch suppressing member is provided on the inner periphery of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body (Fig. 2) and the stretch suppressing member enters the wire space of the coil main body as a result of swelling (Fig. 2)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773